DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 3, 2014

Mortara Instrument, Inc.
c/o Ms. Amy Yang
Sr. Regulatory Affairs Engineer
7865 N. 86th Street
Milwaukee, WI 53224

Re: K141020
Trade/Device Name: Mortara Surveyor S4 Mobile Monitor
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver.
Regulatory Class: Class II
Product Code: DRG
Dated: October 17, 2014
Received: October 20, 2014

Dear Ms. Yang

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141020

Device Name
Mortara Surveyor S4 Mobile Monitor

Indications for Use *(Describe)*
The Surveyor S4 Mobile Monitor is indicated for use:

• The Surveyor S4 mobile monitor is indicated for use in adult & pediatric patient populations. The Mortara Surveyor S4 mobile monitor facilitates the monitoring of ECG signals.
• The Surveyor S4 mobile monitor is a prescription device intended to be used by knowledgeable healthcare professionals within a healthcare facility or clinical pharmacology unit.
• The Surveyor S4 mobile monitor is indicated for use in a clinical setting by a physician, or by trained personnel acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis.
• The Surveyor S4 mobile monitor is indicated for use to acquire and output electrocardiographic data.
• The Surveyor S4 mobile monitor is indicated for use as a radiofrequency physiological signal transceiver, receiving and delivering real-time acquisition and transmission of simultaneous electrocardiographic data, while allowing the patient to be ambulatory within the range of the antenna network.
• The Mortara Li-Ion Battery Charger is intended for charging only the Mortara Rechargeable Li-Ion battery pack.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Notification

510(k): Surveyor S4 Mobile Monitor Device Summary
K141020

Submitter: **Date: November 20, 2014**

Amy Yang, Sr. Regulatory Affairs Engineer
Mortara Instrument, Inc.
7865 N. 86th Street
Milwaukee, WI 53224
FAX: (414) 354-4760
Phone: (414) 354-1600
Contact: Amy Yang (see above)

Trade Name: Mortara Surveyor S4 Mobile Monitor
Common Name: Surveyor S4 Mobile Monitor
Classification Name: Transmitters and receivers, physiological signal, radiofrequency
Classification Description: Radiofrequency physiological signal transmitter and receiver.
Classification Regulation: 21 CFR §870.2910
Product Code: DRG

Legally marketed devices to which S.E. is claimed:

Mortara Surveyor S4 Mobile Monitor	Predicate 510(k) Number	Predicate Manufacturer / Model
Ambulatory X-12 Telemetry Module	K974149	Mortara Instrument, Inc. / X-12 Telemetry Module
T12S Telemetry Transmitter	K081800	Mortara Instrument, Inc. / T12S Telemetry Transmitter

Description:

The Surveyor S4 incorporates wireless electrocardiographic technology to achieve real-time acquisition and RF transmission of simultaneous diagnostic quality 12-lead ECG data to a network access point while allowing the patient to be ambulatory. It provides a means to acquire and transmit 12-lead cardiac signals through the network access point to a compatible monitoring device where the signals are displayed.

The Surveyor S4 Mobile Monitor allows the patient complete freedom of movement. Extended range can be obtained with additional network access points).

The Surveyor S4 Mobile Monitor uses a similar patient cable as the T12S. The S4 requires use of a proprietary ECG patient cable for use with snap electrode hookups. The patient cables use the same wire as present Mortara predicate lead-form cables. The cable is unique to the S4 and is distributed as a device component with the device. The patient cable acquires a continuous ECG signal. A design option will allow the user to set the patient cable type in case of reduced lead (less than 12-lead) options.

ECG patient cable is worn by the patient in a standard torso electrode hook-up, which connects to snap type electrodes. Utilizing a frequency range of 2400.96Mhz to 2482.56MHz, ECG data is acquired, processed and transmitted via a Wi-Fi wireless network comprised of one or more network access points. The wireless network is used for patient data transmission and for other system-level command / control and communication. The data network uses modulation / control schemes that share spectrum based on standard IEEE 802.11 Wi-Fi at 2.5GHz range.

The Surveyor S4 includes data integrity checks and bi-directional error correction protocols to provide robust data transmission. The device also includes a mechanism to inform the user through a compatible centralized monitor of various device states including low battery, lead quality issues, or out of range condition. It has a color, touch-screen display as the primary interface for user input and graphical display of physiological waveforms, measured parameters, demographic data and other status information.

The unit operates with a set of single-use commonly available disposable, non-spillable batteries or from a specified rechargeable battery back that is compatible with applicable standards. The battery charger is capable of charging up to five multi-use (rechargeable) batteries at one time and prevents overcharging.

The Surveyor S4 uses a touch screen user interface for operator interaction that allows control over the device via selection of menu items and icons as well as entry of relevant configuration information. While in normal operation, the display will show other status information such as a battery level indicator, Wi-Fi Signal Strength and Central Station Slot information.

Technology Comparison:

The Mortara Surveyor S4 Mobile Monitor utilizes the same or similar technology for each parameter as utilized by the predicate devices.

Intended Use:

The proposed Mortara Surveyor S4 Mobile Monitor is a prescription device designed to acquire and transmit diagnostic quality ECG in a clinical setting while allowing the patient to be ambulatory. It is suitable for use as a telemetry solution within centralized ECG monitoring systems or other clinical settings for patients connected to telemetry transceivers. It is positioned to be used in the same manner as Mortara Ambulatory X-12 Telemetry Module (K974149), Mortara T12S Telemetry Transmitter (K081800) or other system compatible telemetry transceivers.

The Surveyor S4 Mobile Monitor is designed to work with ECG when used with a compatible multi-parameter Telemetry Central Station System such as the Mortara Surveyor Central Station (K131929) and other compatible receiving devices.

A typical centralized telemetry monitoring system will consist of three main components: the ambulatory ECG telemetry transceivers (e.g. Surveyor S4 Mobile Monitor), compatible network access points comprising an antenna network and the compatible Central Station software application running on a dedicated PC.

The device is intended for use as a patient worn ambulatory telemetry transceiver to be used in hospitals, clinical pharmacology units, and/or clinics for continuous transmission of 12 lead ECG data. Patients are continuously monitored through telemetry, when moving in a defined area, of variable size depending on network access point layout and facility environment. A graphic touch panel color LCD will offer display of physiological waveforms, measured parameters, demographic data and other information.
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The Surveyor S4 Mobile Monitor allows visual ECG display by compatible monitoring devices such as the Mortara Surveyor Central Station (K131929). The cardiac data and analysis displayed by the system is reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with various cardiac rhythm patterns.

Indications for Use:
The Surveyor S4 Mobile Monitor is indicated for use:

- The Surveyor S4 mobile monitor is indicated for use in adult & pediatric patient populations. The Mortara Surveyor S4 mobile monitor facilitates the monitoring of ECG signals.
- The Surveyor S4 mobile monitor is a prescription device intended to be used by knowledgeable healthcare professionals within a healthcare facility or clinical pharmacology unit.
- The Surveyor S4 mobile monitor is indicated for use in a clinical setting by a physician, or by trained personnel acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis.
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- The Mortara Li-Ion Battery Charger is intended for charging only the Mortara Rechargeable Li-Ion battery pack.

Standards and Testing:
Performance testing has been performed on the Mortara S4 Mobile Monitor and demonstrates compliance with International and FDA-recognized consensus standards:

IEC 60601-1:2005 – Medical electrical equipment Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-2:2007 – Medical Electrical Equipment – Part 1-2: General requirements for safety – Collateral Standard: Electromagnetic Compatibility.

IEC 60601-1-6:2010 – Medical Electrical Equipment – Part 1-6: General Requirements for Safety and Essential Performance – Collateral Standard: Usability.

IEC 60601-2-25:2011 – Medical Electrical Equipment. Part 2-25: Particular requirements for the basic safety and essential requirements of electrocardiographs.

IEC 60601-2-27:2011 – Medical Electrical Equipment. Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.

IEC/EN 62304:2006+AC:2008 – Medical device software - Software life-cycle processes.

IEC 62366:2007 – Medical devices - Application of usability engineering to medical devices.

Additionally, verification, validation, performance and environmental tests have been performed to address the intended use, requirement specifications, usability and risk management requirements.

Performance Testing:
Sterilization Validation – The Mortara Surveyor S4 Mobile Monitor is not sterilized or sterilizable, and therefore this section does not apply to the monitor itself.

Shelf Life Testing – The Mortara Surveyor S4 Mobile Monitor is not sterilized or sterilizable, and therefore this section does not apply to the monitor itself.

Biocompatibility Testing – The electrodes, housing and patient cables are parts of the system that come in contact with the patient. These component devices have been previously tested in their own right for other submissions and found to be acceptable. However, the Surveyor S4 Mobile Monitor itself does not involve direct / indirect patient contact.

Software Testing – Software for the Mortara Surveyor S4 Mobile Monitor was designed and developed according to a robust software development process, and was rigorously verified and validated. Test results indicated that the Mortara Surveyor S4 Mobile Monitor complies with its predetermined specification.

Electrical Safety – The Mortara Surveyor S4 Mobile Monitor was evaluated for patient safety in accordance with applicable Standards.

Electromagnetic Compatibility Testing – The Mortara Surveyor S4 Mobile Monitor was tested for EMC in accordance with applicable Standards. Test results indicated that the Mortara Surveyor S4 Mobile Monitor complies with its predetermined specification.

Performance Testing – Bench – The Mortara Surveyor S4 Mobile Monitor was tested in accordance with internal requirements and procedures, and test results indicated that the device complies with the predetermined requirements. This testing includes performance and functional.

Performance Testing – Animal – Animal performance testing was not performed and is not necessary to demonstrate safety and effectiveness of the Mortara Surveyor S4 Mobile Monitor.

Performance Testing – Clinical - Clinical performance testing was not performed and is not necessary to demonstrate safety and effectiveness of the Mortara Surveyor S4 Mobile Monitor.

Conclusion – The results of these activities demonstrate that the Mortara Surveyor S4 Mobile Monitor is as safe, as effective, and performs as well as or better than the predicate device